# *JP XIV*

# THE JAPANESE PHARMACOPOEIA

## *FOURTEENTH EDITION*

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English Version

SOCIETY OF JAPANESE PHARMACOPOEIA

room temperature, and lukewarm are defined as 20°C, 15 - 25°C, 1 - 30°C, and 30 - 40°C, respectively. A cold place, unless otherwise specified, shall be a place having a temperature not exceeding 15°C.

The temperatures of cold water, lukewarm water, warm water, and hot water are defined as not exceeding 10°C, 30 - 40°C, 60 - 70°C, and about 100°C, respectively.

The term "heated solvent" or "hot solvent" means a solvent heated almost to the boiling point of the solvent, and the term "warmed solvent" or "warm solvent" usually means a solvent heated to a temperature between 60°C and 70°C. The term "heat on or in a water bath" indicates, unless otherwise specified, heating with a boiling water bath or a steam bath at about 100°C.

Cold extraction and warm extraction are usually performed at temperatures of 15 - 25°C and 35 - 45°C, respectively.

**9.** To measure the number of drops, a dropping device which delivers 20 drops of Purified Water weighing 0.90 - 1.10 g at 20°C shall be used.

**10.** The term "in vacuum" indicates, unless otherwise specified, a pressure not exceeding 2.0 kPa.

**11.** The acidity or alkalinity of a solution, unless otherwise specified, is determined by blue or red litmus paper. To indicate these properties more precisely, pH values are used.

**12.** The terms in Table 1 are used to express the degree of coarseness or fineness of a powdered medicine.

**Table 1**

| Sieve No. | 4 | 6.5 | 8.6 | 18 | 50 | 100 | 200 |
|---|---|---|---|---|---|---|---|
| Nominal designation of sieve | 4750 μm | 2800 μm | 2000 μm | 850 μm | 300 μm | 150 μm | 75 μm |
| Names of the powders which pass through the respective sieves | Coarse cutting | Medium cutting | Fine cutting | Coarse powder | Medium powder | Fine powder | Very fine powder |

**13.** The water to be used in the tests of drugs shall be Purified Water.

**14.** The name of a solute followed by the word "solution" without indication of the name of the solvent means aqueous solution.

**15.** The concentration of solution expressed as (1 in 3), (1 in 10) or (1 in 100) means the ratio whereby 1 g of a solid or 1 mL of a liquid chemical dissolved in the solvent will make the total volume into 3 mL, 10 mL or 100 mL, respectively. The liquid mixture indicated as (10:1) or (5:3:1) denotes the mixture of 10 and 1 volumes of liquids, or the mixture 5, 3 and 1 volumes of liquids, respectively.

**16.** The term "weigh accurately" means to weigh down to the degree of 0.1 mg, 0.01 mg or 0.001 mg according to the sensitivity in the balance to be used, and the term "weigh exactly" means to weigh to the given decimal places.

**17.** A value of $n$ figures in a test of a drug shall be obtained by rounding from a value of $(n + 1)$ figures.

**18.** Unless otherwise specified, all tests of the drugs shall be performed at ordinary temperature and observations of the results shall follow immediately after the operations. However, the judgment for a test which is affected by temperature should be based on the conditions at standard temperature.

**19.** The terms "immediately" and "at once" used in test of a drug mean that the procedure is to be performed within 30 seconds after the preceding procedure.

**20.** In the section under the heading Description, the term "white" is used to indicate white or practically white, and "colorless" denotes colorless or practically colorless. Unless otherwise specified, the test of color is carried out by placing 1 g of the solid drug on a sheet of white paper or in a watch glass placed on white paper. Liquid drug is put into a colorless test tube of 15-mm inside diameter and is observed in front of a white background through a layer of 30 mm. For the test of clarity of a liquid drugs the same procedure is applied with either a black or white background. For the observation of fluorescence of a liquid drug, only a black background shall be used.

**21.** In the section under the heading Description, the term "odorless' is used to indicate odorless or practically odorless. Unless otherwise specified, the test of odor shall be carried out by placing 1 g of the solid drug or 1 mL of the liquid drug in a beaker.

**22.** In the section under the heading Description, solubilities are expressed in the terms in Table 2. Unless otherwise directed, solubility means the degree of dissolution of drug, previously powdered in the case of a solid, within 30 minutes in a solvent at 20 ± 5°C, by vigorous shaking for 30 seconds each time at 5-minute intervals.

**Table 2**

| Descriptive term | Solvent required for 1 g or 1 mL of solute |
|---|---|
| Very soluble | Less than 1 mL |
| Freely soluble | From 1 mL to 10 mL |
| Soluble | From 10 mL to 30 mL |
| Sparingly soluble | From 30 mL to 100 mL |
| Slightly soluble | From 100 mL to 1000 mL |
| Very slightly soluble | From 1000 mL to 10,000 mL |
| Practically insoluble or insoluble | 10,000 mL and over |